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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/523,776	03/11/2000	Pamela L. Zeitlin	49632 71699	5882
21874	7590	05/20/2004	EXAMINER	
EDWARDS & ANGELL, LLP P.O. BOX 55874 BOSTON, MA 02205				WANG, SHENGJUN
ART UNIT		PAPER NUMBER		
		1617		

DATE MAILED: 05/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/523,776	ZEITLIN ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Shengjun Wang	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

#### A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 16 January 2004.
- 2a) This action is **FINAL**.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-10 and 12-44 is/are pending in the application.
- 4a) Of the above claim(s) 13,14,17-21 and 35-41 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-10,12,15,16,22-34,42-44 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: \_\_\_\_\_

## **DETAILED ACTION**

1. The request filed on January 16, 2004 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/523,776 is acceptable and a CPA has been established. An action on the CPA follows.

1. Claims 13, 14, 17-21, 35-41 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 8 submitted August 30, 2001.

2. the claims have been examined insofar as they read on the elected invention.

### ***Claim Rejections 35 U.S.C. 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:
- The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
4. Claims 6-9, 12, 15, 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
5. Claim 6 recites “a straight carbon chain of about four carbon atoms.” It is unclear what encompassed by “about four.” Will five be considered “about four” how about six, seven, or eight. The claim is indefinite as to the number of carbons encompassed thereby.
6. Claim 12 depends on cancelled claims. The claim is indefinite as to the method it referred to.

***Claim Rejections 35 U.S.C. 102***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

8. Claims 1-5, 12, 15, 16, 22-26, 32-34, 42-44 are rejected under 35 U.S.C. 102(a) as being anticipated by Faller et al. (WO 99/40883)

9. Faller teaches a method of treating cystic fibrosis comprising administering to a composition comprising butyric acid derivatives, e.g., cinnamic acid. See, particularly, the abstract and the claims.

***Claim Rejections 35 U.S.C. 103***

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 1-10, 12, 15-16, 22-34 and 42-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Herron (US Patent 4,764,521) in view of Rubenstein et al (IDS, CJ) and Welchter et al. (U.S. Patent 5,981,592).

12. Herron teaches generally that substituted aryl carboxylic acids, including substituted 4-phenyl-3-butenoic acid are known to be useful for treating respiratory disease such as cystic fibrosis. See, the abstract, columns 1-4, column 12, lines 5, column 17, lines 50-52.

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13. Herron does not teach expressly the employment of unsubstituted aryl carboxylic acid, e.g., 4-phenyl-trans-3-butenoic acid for treatment of cystic fibrosis.

14. However, Rubenstein et al. teaches unsubstituted aryl carboxylic acid, 4phenylbutyric acid is also known to be useful for treatment of cystic fibrosis. See, particularly, the abstract. Wechter et al. further teaches that a variety of aryl carboxylic acids are known to be useful for treatment of cystic fibrosis. See, the abstract, columns 6-7.

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to employ 4-phenyl-trans-3-butenoic acid for treating cystic fibrosis.

A person of ordinary skill in the art would have been motivated to employ 4-phenyl-trans-3-butenoic acid for treating cystic fibrosis because aryl carboxylic acids, with substituent or without substituent on the aryl ring , and wherein the carboxyl group attached to the aryl group through either alkyl or alkenyl, are generally known to be useful for treating cystic fibrosis. The instant compound differing from the prior art compound only in the substituent on the aryl ring, or the double bond at the linker between the aryl and carboxylic group, would have been reasonably expected to be similarly useful for treating cystic fibrosis, absent evidence to the contrary. Regarding claim 22-23, note selecting and/or optimizing a administering method of a pharmaceutical agent is considered within the skill of artisan.

15. Claims 6-10 and 27-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Faller et al. (WO 99/40883).

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16. Faller teaches a method of treating cystic fibrosis comprising administering to a composition comprising butyric acid derivatives, e.g., cinnamic acid. See, particularly, the abstract and the claims.

17. Faller does not teach expressly to employ the particular compounds herein, e.g., 4-phenyl-3-butenoic acid.

18. The reference teaches certain compounds that are structural homologs of the instantly claimed compounds, i.e., they differ only by a CH<sub>2</sub> group. Cinnamic acid differs from 4-phenyl-3-butenoic acid by a methylene moiety. The instant compounds are structural homologs of the reference compounds. One having ordinary skill in the art would have been motivated to prepare the instantly claimed compound because such structurally homologous compounds are expected to possess similar properties. It has been held that compounds that are structurally homologous to prior art compounds are *prima facie* obvious, absent a showing of unexpected results. *In re Hass*, 60 USPQ 544 (CCPA 1944); *In re Henze*, 85 USPQ 261 (CCPA 1950).

#### *Response to the Arguments*

Applicants' amendments and remarks submitted January 16, 2004 have been fully considered, but are not persuasive for reasons discussed below.

19. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

20. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the teaching suggestion and motivation are found both in the cited references. Particularly, Herron teaches the compounds herein for treating disorder characterized by an excessive release of leukotriene, and cystic fibrosis is disclosed as one of those disorders. The second references teaches that compounds having common structural features with those disclosed by Herron are particularly known for treating cystic fibrosis. Therefore, the employment of Herron's method for treating cystic fibrosis would have been obvious. As to the particular compounds recited in the dependent claims, note since they are structurally similar to those disclosed by the cited references (with carboxylic group and an aromatic ring), they would have reasonably expected to be similarly useful.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang, Ph.D. whose telephone number is (571)272-0632. The examiner can normally be reached on Monday-Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (571)272-0629. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9302.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

SHENGJUN WANG  
PRIMARY EXAMINER

S. 

Shengjun Wang

May 14, 2004